Federal Regulatory Fact Sheet Series

Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine

Laws Enforced by the Center for Veterinary Medicine:
Federal Food, Drug, and Cosmetic Act (FFDCA)
Amendments to FFDCA
Minor Use and Minor Species Act of 2004
Animal Drug User Fee Act
Animal Generic Drug User Fee Act

The Center for Veterinary Medicine (CVM) regulates the manufacture and distribution of food additives and drugs that will be given to animals. These include animals from which human foods are derived, as well as pet (or companion) animals. CVM is responsible for regulating drugs, devices, and food additives given to, or used on, over one hundred million companion animals, plus millions of poultry, cattle, swine, and minor animal species, **including fish** (Minor animal species include animals other than cattle, swine, chickens, turkeys, horses, dogs, and cats). Several offices within the Center for Veterinary Medicine (CVM) play a role with a regard to aquaculture.

- The Office of New Animal Drug Evaluation (ONADE**)** works with various government agencies and aquaculture associations to increase the number of safe and effective drugs that can be used by the aquaculture industry. As mandated by the FFDCA, a new animal drug may not be sold in interstate commerce unless it is the subject of an approved new animal drug application (NADA) or abbreviated NADA (ANADA), there is a conditional approval (CNADA) or it is on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species. The three types of NADAs are reviewed by ONADE. During the investigational stages of drug development, ONADE may also authorize investigational new animal drug (INAD) exemptions to allow for the use of the drug to generate data to support an approval. Part 21 of the Code of Federal Regulations describes the regulations associated with NADAs and INADs.
- With the passage of the Minor Use and Minor Species Animal Health Act of 2004, the Office of Minor Use and Minor Species Animal Drug Development (OMUMS) plays a critical role in making more drugs legally available to veterinarians and animal owners to treat minor animal species such as fish. OMUMS administers the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index). The Index is a list of new animal drugs intended for use in non-food producing minor species (e.g., ornamental fish) that have had their safety and effectiveness affirmed through an alternate review process involving expert panels external to FDA. OMUMS also manages the MUMS Designation program which provides incentives for sponsors to seek approval of new animal drugs for MUMS indications.
- The Office of Research (OR) conducts aquaculture research in a state-of-the-art facility and assists in assuring that fish derived from aquaculture production environments are safe for human consumption.

- The Office of Surveillance and Compliance (OSC) is responsible for compliance-related actions, post-approval monitoring (e.g., adverse drug event reporting), and animal feed safety. OSC reviews notices that a substance (including an aquaculture feed substance) is Generally Recognized as Safe (GRAS) for a specific use within an animal food, approves Food Additive Petitions (FAP), and regulates medicated animal feeds (i.e., feeds that contain a new animal drug). A Medicated Feed Mill License is required to manufacture some medicated feeds. These licenses are also approved by OSC.
- Under the new animal drug provisions of the FFDCA, CVM has the authority to regulate genetically engineered (GE) animals, which includes genetically engineered fish and shellfish.

Agency Website: www.fda.gov/animalveterinary

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